Remarks

Status of the Specification and Drawings

In the specification, the sequence listing as filed in the Preliminary Amendment filed in the present application on May 17, 2007, has been replaced with a substitute sequence listing. Figure 5 has been amended to include sequence identifier information. The sequence listing has been amended to include the sequence of VhhM-lC8. Support for this amendment can be found in originally filed Figure 5. These amendments are sought to correct minor informalities in the specification. Thus, these amendments add no new matter, and their entry and consideration are respectfully requested. In accordance with 37 C.F.R. §§ 1.821-1.825, the computer readable and paper copies of the substitute sequence listing submitted herewith are the same and include no new matter.

Status of the Claims

Upon entry of the foregoing amendments, claims 1-14 are pending in the application, with claim 1 being the sole independent claim. Claims 9 and 13 have been withdrawn as being drawn to a nonelected restriction group, the Restriction Requirement having been made final in the present Office Action.

By the foregoing amendments, claims 1-13 are sought to be amended. Support for the amendments to claims 1-8, 10 and 13 can be found throughout the application as filed, *e.g.*, at page 6, lines 21-23; at page 10, lines 8-10; at page 19, lines 8-9, 18-20, 25-26; and at page 19, line 36 to page 20, line 2. Amendments to claims 11 and 12 are sought to provide an antecedent basis for the term "detergent." New claim 14 is sought to be introduced. Support for new claim 14 can be found throughout the application as

filed and in original claim 8. These changes are believed to introduce no new matter, and their entry and consideration are respectfully requested.

Summary of the Office Action

In the Office Action, the Examiner has made one objection to the specification and drawings, and four rejections of the claims. Applicants respectfully offer the following remarks with respect to each of these portions of the Office Action.

Objection to the Specification and Drawings

At page 3 of the Office Action, the Examiner has objected to the specification and drawings for lacking sequence identifiers. By the foregoing amendments, Figure 5 has been amended to include sequence identifiers that were previously omitted. In addition, the sequence listing has been amended to reflect sequences included in the specification as originally filed, as required by the Examiner in the Office Action. As noted above, these amendments add no new matter.

Accordingly, the objection has been accommodated; Applicants therefore respectfully request that the objection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 101

At page 3 of the Office Action, the Examiner has rejected claims 1-8 and 10-12 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The Examiner contends that the claims of the presently claimed invention "do not sufficiently distinguish over proteins as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products." *See* Office Action at page 3, final paragraph.

Solely to advance prosecution and not in acquiescence to the Examiner's contentions and conclusions, claim 1 (and hence claims 2-8 and 10-12 that ultimately depend therefrom) has been amended to recite "an isolated fusion protein." Applicants respectfully contend that the claims as currently presented distinguish proteins as they exist naturally, as the latter are not "isolated." Hence, the present claims fully comply with the requirements of 35 U.S.C. § 101.

Therefore, Applicants respectfully request that the rejection of claims 1-8 and 10-12 be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

At page 4 of the Office Action, the Examiner has rejected claims 3 and 8 as allegedly being indefinite and failing to particularly and distinctly claim the subject matter. The Examiner contends that the phrase "such as" renders claim 3 vague and indefinite. The Examiner further contends that the phrase "preferably 2-5 amino acids" renders claim 8 vague and indefinite. Applicants respectfully disagree.

However, in order to further prosecution and not in acquiescence to the Examiner's contentions and conclusions, claims 3 and 8 have been amended to remove the phrases noted above, that were the basis for this rejection. Hence, claims 3 and 8 as currently presented are not indefinite; Applicants therefore respectfully request that the rejection of claims 3 and 8 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

Rejection Under 35 U.S.C. § 112, First Paragraph

At pages 4-5 of the Office Action, the Examiner has rejected claims 1-8 and 10-12 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

The Examiner contends that Applicants are not in possession of the claimed genus, stating that:

> [t]he claims are genus claims encompassing a genus of fusion proteins comprising a genus of carbohydrate binding domains and a genus of domains having a high affinity for a microcapsule comprised of or containing a melamine based chemical component.

Office Action at page 5, second paragraph. The Examiner further contends that each genus includes "members with widely differing amino acid sequences and structures from many biological sources." The Examiner further asserts that "the specification . . . does not describe and define any structural features, amino acid sequences, and/or biological functions that are commonly possessed by members of each genus." *Id.* The Examiner contends that while Applicants have disclosed several melamine-binding proteins this is "insufficient to be representative of the attributes and features common to all the members of each claimed genus." *See* Office Action at page 5, third paragraph. Applicants respectfully disagree with the Examiner's contentions and conclusions.

The present specification provides a clear definition of fusion proteins which comprise a carbohydrate binding domain and a domain having a high affinity for a microcapsule comprising a melamine based chemical compound. *See* present specification at page 3, line 24 to page 11, line 21. Applicants submit that based on the description contained in the present specification, a person of ordinary skill in the art

would readily recognize what subject matter is encompassed by the present claims, and that Applicants were therefore clearly in possession of the claimed fusion proteins. Applicants submit that the present specification provides numerous examples of bifunctional fusion proteins that are capable of binding to carbohydrates and a melamine-type polymer. *See, e.g.*, present specification at pages 3-11. Applicants assert that one of ordinary skill in the art would readily understand that the fusion proteins of the presently claimed invention comprise (1) a carbohydrate binding domain; and (2) a domain having a high affinity for a melamine-type polymer. The carbohydrate binding domain of the claimed fusion proteins can bind to a variety of carbohydrates, including, but not limited to, cellulose, starch, mannose, xylan and chitin. *See* specification at page 4, lines 4-8. Furthermore, the presently claimed fusion proteins comprise a domain that specifically binds a melamine-type polymer, non-limiting examples of which are fully described in the present specification, *e.g.*, at page 12, line 28 through page 13, line 26. Thus, the fusion proteins of the presently claimed invention encompass numerous variations of fusion proteins that are capable of binding to various carbohydrates via the carbohydrate binding domain, and specifically binding to melamine-type polymers via a domain having a high binding affinity for melamine. In addition, the present specification provides methods of preparing such fusion proteins (*see, e.g.*, present specification at page 5, line 33 through page 6, line 4; page 9, line 1 through page 10, line 12; page 11, lines 6-21; and Example 1).

As the Federal Circuit has held, the written description requirement must be viewed in light of the state of the art at the time of filing. *Capon v. Eshhar,* 418 F.3d 1349, 1357-1358 (Fed Cir. 2005) ("[t]he descriptive text needed to meet these [written

description] requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence."). As noted above, the present specification fully describes the structure of exemplary fusion proteins of the presently claimed invention. As also noted above, the present specification fully describes methods of making the presently claimed fusion proteins. Thus, in view of the teachings provided by the present specification, one of ordinary skill would readily conclude that Applicants were clearly in possession of the full scope of the presently claimed invention at the time of filing of the present application.

Applicants submit that *Capon* clarifies the written description requirement as delineated by *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993); *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991); and *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559 (Fed. Cir. 1997). In discussing the current state of the written description requirement under 35 U.S.C. §112, first paragraph, the Federal Circuit stated "[s]ince the law is applied to each invention *in view of the state of relevant knowledge*, its application will vary with differences in the state of knowledge in the field . . . ." *Capon*, 418 F.3d at 1357-1358 (emphasis added). In reviewing and overturning the Board's decision, the Federal Circuit held that "[t]he Board erred in refusing to consider the state of scientific knowledge . . . ." *Id.* Furthermore, the Federal Circuit stated that the Board's reliance on *Eli Lilly, Fiers, Amgen v. Chugai* and *Enzo Biochem Inc., v. GenProbe, Inc.*, 296 F.3d 1316 (Fed. Cir. 2002) for the case at bar was incorrect and explained that "[n]one of the cases to which the Board attributes the requirement of total DNA re-analysis, *i.e.*, *Regents v. Lilly, Fiers*

v. Revel, Amgen [*v. Chugai*], *or Enzo Biochem*, require a re-description of what was already known." *Id.*

Moreover, the Federal Circuit has stated that:

> The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the *same way*. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution. Both Eshhar and Capon explain that this invention does not concern the discovery of gene function or structure, as in *Lilly*. The chimeric genes here at issue are prepared from *known* DNA sequences of *known* function. The Board's requirement that these sequence must be analyzed and reported in the specification *does not add descriptive substance.*

Id. at 1358 (emphasis added).

The fusion proteins of the presently claimed invention comprise a combination of a carbohydrate binding domain and a domain that has a high affinity for a melamine-type polymer that are readily produced using *known* methods and techniques (*e.g.*, those methods and techniques set forth at page 5, line 33 through page 6, line 4; page 9, line 1 through page 10, line 12; and page 11, lines 6-21 of the present specification). Describing every fusion protein that could be prepared in the practice of the present invention would not add descriptive substance to the present application, and hence is not required under *Capon*. *See id.* Indeed, it is irrelevant whether or not the present specification provides an exhaustive list for all possible embodiments of the claimed fusion proteins -- the statute does not require such a level of teaching.

Applicants therefore respectfully submit that the state of the art as of the filing date of the present application was such that when reading the present specification in the context of that knowledge in the art, one of ordinary skill would readily recognize that a

substantial number of fusion proteins having the common attributes of a carbohydrate domain and a domain having a high affinity for a melamine-type polymer could be prepared and used in accordance with the disclosure of the specification. Accordingly, Applicants submit that the present specification adequately and sufficiently describes the presently claimed invention, and hence, fully meets the written description requirements of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Rejection Under 35 U.S.C. § 103 Over Davis in View of Uchiyama and Westergrove

At pages 7-8 of the Office Action, the Examiner has rejected claims 1-8 and 10-12 as allegedly being unpatentable over Davis *et al.*, International Publication WO 01/46357 (hereinafter "Davis"), in view of Uchiyama *et al.*, International Publication WO 03/089019 (hereinafter "Uchiyama") and Wetegrove *et al.*, U.S. Patent No. 5,593,850 (hereinafter "Wetegrove"). Applicants respectfully traverse this rejection.

The Examiner alleges that Davis discloses a fusion protein comprising a cellulose binding domain and a domain having a high affinity for another ligand. The Examiner further asserts that the domain can include peptides and antibodies (*e.g.*, a Heavy Chain antibody found in *Camelidae*) that are specific for "almost any protein, organic molecule, or cell surface that is likely to be encountered." *See* Office Action at page 7, second paragraph. The Examiner further asserts that the cellulose binding domain and a domain having a high affinity for another ligate can be connected via a linker, and that Davis discloses detergent compositions that are capable of delivering a benefit agent (*e.g.*,

perfumes, fragrances, lubricants, and photoprotective agents) to a fabric during a washing or rinsing process. *Id.*

However, the Examiner concedes that Davis does *not* disclose a domain having high binding affinity for a microcapsule comprising a melamine based chemical component. *See* Office Action at page 7, third paragraph. The Examiner relies on the disclosure of Uchiyama to cure this deficiency, asserting that Uchiyama allegedly discloses "malodor-controlling compositions comprising microcapsules having melamine as chemical component and their use as carriers of benefit agents including perfume and odor control agent." *See* Office Action at page 7, fourth paragraph.

The Examiner further relies on the disclosure of Wetegrove to establish a *prima facie* case of obviousness. Wetegrove allegedly discloses "generation of monoclonal antibodies to polymers." *See* Office Action at page 8, first paragraph.

The Examiner concludes that it would have been obvious to modify the fusion protein disclosed in Davis to have a high binding affinity to the microcapsules disclosed in Uchiyama that have melamine as a chemical component. The Examiner further concludes that one would have been motivated to combine the disclosures of Davis and Uchiyama "in order to have a fusion protein that will allow for delivery of a benefit agent such as a perfume and odor control agent to a surface such as a fabric . . . . ." *See* Office Action at page 8, second paragraph. Additionally, the Examiner concludes that "[o]ne of ordinary skill in the art has a reasonable expectation of success since Davis et al. teach the successful construction of fusion proteins . . ., and US Patent 5,593,850 teaches

successful generation of monoclonal antibodies to polymers." *Id.* Applicants respectfully disagree with the Examiner's contentions and conclusions.

Present claim 1 (and hence, claims 2-8 and 10-12 that depend ultimately therefrom), recite an isolated fusion protein comprising a Carbohydrate Binding Domain and a domain having a *high binding affinity for a microcapsule comprising a melamine based chemical component*. Applicants respectfully submit that Davis, Uchiyama and Wetegrove, alone or in combination, do not disclose or suggest the presently claimed invention.

"Under § 103, the scope and content of the prior art is to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). Applicants respectfully submit that the differences between the presently claimed invention and the references cited by the Examiner are so great that it would not have been obvious to modify the disclosure of Davis using those of Uchiyama and Wetegrove in order to make and use the presently claimed invention.

As set forth above, and as the Examiner concedes, Davis does not disclose or suggest an isolated fusion protein having high binding affinity for a microcapsule comprising a melamine based chemical component, as required by the presently claimed invention. As a result, Davis is deficient as a primary reference upon which to base a *prima facie* case of obviousness.

Applicants respectfully submit that Uchiyama does not cure this deficiency in Davis. Although Uchiyama may disclose microcapsules that can contain melamine as a chemical component, Uchiyama fails to provide any disclosure or suggestion of the structure of *any* protein, let alone a fusion protein, that has a domain having a high binding affinity for a microcapsule comprising a melamine based chemical component. Moreover, Uchiyama provides no disclosure or suggestion that such fusion proteins could or even should be produced. Hence, Uchiyama provides no disclosure which would have led a person of ordinary skill in the art to prepare an isolated fusion protein comprising a Carbohydrate Binding Domain and a domain having a high binding affinity for a microcapsule comprising a melamine based chemical component, as required by the presently claimed invention.

Applicants also respectfully submit that Wetegrove does not cure the deficiency of Davis, alone or in combination with Uchiyama. Wetegrove merely discloses that monoclonal antibodies that are directed to polymers can be prepared, but fails to suggest or disclose *any* antibodies that specifically bind melamine. Thus, Wetegrove, in combination with Davis and Uchiyama, *does not* disclose or suggest the presently claimed invention.

Applicants respectively submit that the Examiner's contention that a person of ordinary skill in the art would have been motivated to combine the disclosures of Davis and Uchiyama in order to prepare an isolated fusion protein recited in the present claims can only be based on Applicants' own disclosure and impermissible hindsight, since the references themselves do not provide the necessary information to pick and choose parts

of their disclosures to combine, as the Examiner has done in making the present rejection. *See* M.P.E.P. § 2145(X)(A). As the Federal Circuit has held numerous times, such a hindsight-based analysis is impermissible. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) ("When prior art references require selective combination by the [fact-finder] to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.").

In *KSR Int'l Co v. Teleflex Inc.*, the Supreme Court also cautioned against the use of hindsight in support of an obviousness rejection. *See* 127 S.Ct. 1727, 1742 (2007) ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant on *ex post* reasoning."). Thus, the hindsight analysis relied upon in the present rejection is impermissible, and cannot be used to attempt to establish a *prima facie* case of obviousness.

In summary, Applicants respectfully submit that the fusion proteins disclosed in Davis would not have led one of ordinary skill in the art to specifically prepare the presently claimed isolated fusion proteins comprising a Carbohydrate Binding Domain and a domain having a high binding affinity for a microcapsule comprising a melamine based chemical component, as compared to "almost any protein, organic molecules or cell surface that is likely to be encountered." *See* Office Action, page 7, second paragraph. Moreover, merely recognizing that the microcapsules of Uchiyama can contain melamine as a chemical component does *not* provide a person of ordinary skill with any guidance required to prepare an isolated fusion protein of the present claims.

Additionally, Wetegrove does not provide any further guidance to one of ordinary skill in the art to make and use the isolated fusion proteins of the presently claimed invention. Furthermore, it is only based on impermissible hindsight using Applicants' own specification that one of ordinary skill would even have been directed to pick and choose portions of these cited references in the attempt to prepare and use the presently claimed fusion proteins which is impermissible. *See* M.P.E.P. § 2145(X)(A). Moreover, even if such hindsight analysis *was* permissible, one of ordinary skill *still* would not have been able to make and use the presently claimed invention, since the cited references are seriously deficient with respect to the presently claimed fusion proteins. Thus, Applicants respectfully submit that based solely on the cited references, a person of ordinary skill in the art would not have prepared (and indeed, would not have been *able* to prepare) isolated fusion proteins comprising a Carbohydrate Binding Domain and a domain having a *high binding affinity for a microcapsule comprising a melamine based chemical component* as set forth in the present claims. Hence, the Examiner has not set forth a *prima facie* case of obviousness.

Therefore, the disclosures of Davis, Uchiyama and Wetegrove do not render obvious the presently claimed invention, as none of the references, alone or in combination, discloses the presently claimed invention. Applicants respectfully assert that the Examiner has not established a *prima facie* case of obviousness and request that the rejection be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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